

DETAILED ACTION

Drawings

1. The drawings were received on 7 April 2008. These drawings are accepted.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 5-7, 9-13, 16, 21, 22, 24, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,409,708 to Wessman in view of US 5,041,087 to Loo et al.

In the specification and figures, Wessman discloses the apparatus substantially as claimed by applicant. With regard to claims 1 and 16, Wessman discloses a giving set cap 10 that provides fluid communication between vessel 20 and chamber 12. The cap comprises a delivery tube with a main channel 13 for fluid delivery and a subsidiary channel 14 for fluid delivery. The cap comprises inlet/outlet openings at the top or outer wall of each channel that are spaced to allow sufficient mixing as claimed by applicant. The outlet of subsidiary channel 14 is disposed on a bevel, making it an oval-shaped opening in an outer (top) wall of the cap, wherein the opening faces away from the main channel (see FIG 2). Subsidiary channel 14 comprises an inlet 16 that is disclosed as being pierced by a needle.

Wessman fails to disclose that the subsidiary inlet 16 is adapted to receive a needleless syringe. However, Loo discloses a fluid connector 56 with an injection port or subsidiary inlet 20 with a male luer lock end 22 configured for access with a needleless syringe in order to prevent accidental needle sticks (see columns 1-2, FIG 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add the needleless connector disclosed by Loo to the connector disclosed by Wessman in order to prevent accidental needle sticks, as taught by Loo.

Wessman and Loo fail to disclose the 25mm distance between the inlet and the outlet of the main channel. However, it has been held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. See MPEP 2144.04(IV)(A). In the instant case, it appears that the distance between the openings as disclosed and illustrated by Wessman provides sufficient distance for mixing as claimed by applicant, rendering the distance claimed by applicant an unpatentable improvement over the prior art device.

With regard to claims 2-3, Wessman is silent as to the distance between the openings of the main and subsidiary channels. However, it has been held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. See MPEP 2144.04(IV)(A). In the instant

Art Unit: 3761

case, it appears that the distance between the openings as disclosed and illustrated by Wessman provides sufficient distance for mixing as claimed by applicant, rendering the distance claimed by applicant an unpatentable improvement over the prior art device. With regard to claim 2, Applicant claims the intended use of the claimed apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, the apparatus suggested by the prior art is capable of permitting fluid flow in the manner claimed by applicant, thereby meeting the limitations of the claims.

With regard to claims 5-7, 9, 12, 22, 24, and 33, Wessman illustrates connector means at 10 that attaches the cap to chamber 12, and tapered sharp or piercing ends of insertion portion or delivery tubing 11 that allow the cap to be inserted into container 20 (see FIGS 1-2). Main channel 13 extends through connector means at 10, terminating in an outlet.

With regard to claims 10-11, it has been held that the mere duplication of the parts of a device disclosed by the prior art has no patentable significance unless a new and unexpected result is produced. See MPEP 2144.04(VI)(B). In the instant case, applicant fails to disclose a new and unexpected result from the multiple inlets, rendering the claimed inlets unpatentable over the prior art.

With regard to claims 13 and 21, subsidiary channel 14 inlet (generally at 15) is located within the periphery of the connecting means, with a channel extending to the side of the connector.

4. Claims 14-15, 18, 20, 26, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,409,708 to Wessman in view of US 5,041,087 to Loo et al, further in view of US 3,662,752 to Yokoyama.

In the specification and figures, Wessman and Loo disclose the apparatus substantially as claimed by applicant (see rejection above) with the exception of a detachable vent cap over the subsidiary inlet. Yokoyama discloses an infusion device with a needle 7 comprising a medicament passage from one chamber to another comprising a subsidiary inlet 17. Attached to the inlet 17 is a removable cap 29 with a filter 30 therein to provide sterile communication with the atmosphere for venting (see column 2, FIGS 1-4). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a detachable venting cover as disclosed by Yokoyama to the infusion connector suggested by the prior art in order to provide a sterile vent, as taught by Yokoyama.

With regard to claims 26 and 36, Wessman and Loo disclose the apparatus substantially as claimed by applicant (see rejection above) with the exception of an outlet formed in the outer wall of the subsidiary channel proximate to but removed from the distal tip of the channel. Yokoyama discloses a delivery apparatus wherein channel 3 comprises an opening 5 in the outer wall of the channel removed from the distal end of the channel. All the elements of the claimed apparatus are known in the art, and one of ordinary skill in the art could have combined the known elements by known methods, with no change in their respective functions, wherein the combination would yield only predictable results. In the instant case, it would have been obvious to move the oval-

Art Unit: 3761

shaped opening in the subsidiary channel disclosed by Wessman to a sidewall of the channel, as disclosed by Yokoyama, since the elements are known in the art, and such a movement would not change any of the respective functions of the elements, yielding the predictable result of a connector with a sidewall opening.

5. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,409,708 to Wessman in view of US 5,041,087 to Loo et al, further in view of US 4,623,343 to Thompson.

In the specification and figures, Wessman and Loo suggest the apparatus substantially as claimed by applicant (see rejection above) with the exception of internal threads on the connector to attach the giving set cap to drip chamber 12. Threaded connections between fluid passageways are well known in the art of fluid infusion, as demonstrated by Thompson, who discloses a threaded connection 54 between fluid syringe 12 and connector 12 (see FIG 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to provide a threaded connection between the subsidiary channel inlet and the vent cap, since such connections are well known in the art.

6. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,409,708 to Wessman in view of US 5,041,087 to Loo et al, further in view of US 4,687,473 to Raines.

In the specification and figures, Wessman and Loo disclose the apparatus substantially as claimed by applicant (see rejection above) with the exception of a line attached to the drip chamber. It is well known in the art of infusion to attach an infusion

line to drip chambers for patient infusion, as illustrated by Raines (see drip chamber 27 attached to infusion tubing line 29 in FIGS 1-2). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add an infusion line as disclosed by Raines to the giving set cap or connector with drip chamber as suggested by the prior art in order to allow for patient infusion.

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,409,708 to Wessman in view of US 5,041,087 to Loo et al in view of US 3,662,752 to Yokoyama, further in view of US 4,623,343 to Thompson.

In the specification and figures, Wessman, Loo, and Yokoyama suggest the apparatus substantially as claimed by applicant (see rejection above) with the exception of threads to attach the vent cap to the subsidiary channel inlet. Threaded connections between fluid passageways are well known in the art of fluid infusion, as demonstrated by Thompson, who discloses a threaded connection 54 between fluid syringe 12 and connector 12 (see FIG 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to provide a threaded connection between the subsidiary channel inlet and the vent cap, since such connections are well known in the art.

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,409,708 to Wessman in view of US 5,041,087 to Loo et al in view of US 3,662,752 to Yokoyama, further in view of US 4,687,473 to Raines.

In the specification and figures, Wessman, Loo, and Yokoyama suggest the apparatus substantially as claimed by applicant (see rejection above) with the exception

of a vent cap attached to the device by means of a hinge. Raines discloses a fluid infusion kit with a port 19 and cap 21 attached to the housing with a tether or hinge 38 to prevent loss of the cap (see FIGS 2, 2A). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a tether or hinge as disclosed by Raines to the infusion connector with vent cap as suggested by the prior art in order to prevent loss of the cap.

9. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,409,708 to Wessman in view of US 5,041,087 to Loo et al, in view of US 3,662,752 to Yokoyama, further in view of US 4,687,473 to Raines.

In the specification and figures, Wessman and Loo disclose the apparatus substantially as claimed by applicant (see rejection above) with the exception of a line attached to the drip chamber. It is well known in the art of infusion to attach an infusion line to drip chambers for patient infusion, as illustrated by Raines (see drip chamber 27 attached to infusion tubing line 29 in FIGS 1-2). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add an infusion line as disclosed by Raines to the giving set cap or connector with drip chamber as suggested by the prior art in order to allow for patient infusion.

10. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,409,708 to Wessman in view of US 5,041,087 to Loo et al, in view of US 3,662,752 to Yokoyama, in view of US 4,687,473 to Raines, further in view of US 4,623,343 to Thompson.

11. In the specification and figures, the cited prior art suggests the apparatus substantially as claimed by applicant (see rejection above) with the exception of a vent cap attached to the device by means of a hinge and thread to attach the vent cap to the subsidiary channel inlet. Raines discloses a fluid infusion kit with a port 19 and cap 21 attached to the housing with a tether or hinge 38 to prevent loss of the cap (see FIGS 2, 2A). Threaded connections between fluid passageways are well known in the art of fluid infusion, as demonstrated by Thompson, who discloses a threaded connection 54 between fluid syringe 12 and connector 12 (see FIG 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to provide a threaded connection between the subsidiary channel inlet and the vent cap with a tether or hinge as disclosed by Raines in order to connect the infusion connector with vent cap and prevent loss of the cap.

Response to Arguments

12. Applicant's arguments filed 7 April 2008 have been fully considered but they are not persuasive.

13. Applicant argues that the combination of Wessman and Loo fail to disclose an apparatus with sufficient spacing between the inlet and outlet to allow for sufficient inherent mixing of fluids. However, Applicant has not provided any objective evidence to support the allegation that the instantly claimed invention provides the mixing desired by applicant. Though Wessman discloses that infusion may be started "after mixing contents of the bag," it does not specifically disclose that external mixing forces are

required. Mixing may have been caused by the injection step. Since Wessman does not specifically teach that external forces are required to mix the container contents, it is the position of the Examiner that the inlet openings disclosed by Wessman may be sufficiently spaced to allow for the mixing desired by applicant.

14. Applicant argues that Loo discloses an inlet for a needleless syringe that allows only for the injection of fluid downstream from the mixing chamber. However, the Examiner is not relying on the Loo reference to teach the position of the subsidiary channel. The Examiner relies on Loo only to teach that the cap 16 disclosed by Wessman may be substituted with a cap 22 that accommodates a needleless syringe as taught by Loo. The location of the inlet disclosed by Loo does not teach away from the combination of the delivery set disclosed by Wessman and the cap disclosed by Loo.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner
Art Unit 3761
9 June 2008